Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-07-23
Investment Auto Submission Date: 2012-02-24
Date of Last Investment Detail Update: 2011-09-16
Date of Last Exhibit 300A Update: 2012-07-23
Date of Last Revision: 2012-07-23

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 02

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA OC-OIM Information and Computing Technologies for the 21st Century (ICT21)

2. Unique Investment Identifier (UII): 009-000005354

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

Development of new information technologies, driven by accelerating computational processing & substantial growth in data volume, is causing transformation to all aspects of the FDA operations. New types & vastly larger quantities of data to be processed by the FDA, from multiple clinical & diagnostic endpoints from industry submissions & collaborations with other research sources, reuse of existing data within & among the FDA centers & other government agencies (i.e. NIH, CMS, CDC, VA, DoD, etc.), & outside entities including foreign countries, are examples of the complexity & number of information sources the FDA handles today. The number of sources & data elements increases as the need for complex inputs for safety evidence & efficacy information, genomics, metabolic network & clinical trials modeling, data markers type data, integrated data & networks, & food imports expands. The FDA is increasing its use of electronic health records data to acquire pertinent information for its pharmacovigilance efforts causing expanded participation in programs & initiatives to define of the records standards & networks to assure appropriate data are gathered for use in such activities as safety & efficacy, & genomics & data markers. To meet these challenges, the FDA is modernizing its capacity & communication capabilities by creating an agency-wide bioinformatics IT platform. The ICT21 Initiative designs & builds this purpose driven, data centric environment for the FDA. The imitative increases the Agency’s capabilities to:

respond to emerging technologies & challenges, strengthen product development & approval, improve manufacturing & product quality, strengthen post-approval surveillance & safety, support electronic prescribing, & improve clinical decision making. Results are achieved by collecting & combining clinical & other important & pertinent data from industry, government agencies & outside entities into integrated databases & networks to expand the scientific computations & computational sciences at the FDA. The FDA continues to widen the use of analytics for large datasets which integrate multiple clinical & diagnostic endpoints, through increased use of clustering & grid computing to improve collaboration among & within entities interacting with the FDA. The new ICT21 bioinformatics platform supports the FDA's growing mission within 2–10 years & the PMA goal-Expanded e-Government - Disaster Management, & the DHHS goal of increasing scientific R&D.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

The ICT21 Initiative designs & builds this purpose driven, data centric environment for the FDA. The Initative increases the Agency's capabilities to: respond to emerging technologies & challenges, strengthen product development & approval, improve manufacturing & product quality, strengthen post-approval surveillance & safety, support electronic prescribing, & improve clinical decision making. Results are achieved by collecting & combining clinical & other important & pertinent data from industry, government agencies & outside entities into integrated databases & networks to expand the scientific computations & computational sciences at the FDA. The FDA continues to widen the use of analytics for large datasets which integrate multiple clinical & diagnostic endpoints, through increased use of clustering & grid computing to improve collaboration among & within entities interacting with the FDA. The new ICT21 bioinformatics platform supports the FDA's growing mission within 2–10 years & the PMA goal-Expanded e-Government - Disaster Management, & the DHHS goal of increasing scientific R&D.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

PCOR: Legacy data converted; PACES workshop conducted and study design delivered as part of collaboration with academia for Patient-Centered Outcomes Research (PCOR); installed modern analytical tools. Janus: Collaborate with NIH/NCI on the Janus Clinical Trials Repository (Janus CTR); Data model design drafted; initiated transition planning for CTR. SE: First scientific enclave (SE) pilot completed as a cross-center and inter-agency collaboration with CDC. DCM: Data center consolidation and migration (DCM) to a modernized platform ongoing. HPC: O&M of implemented high performance computer (HPC) in FY10.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

PCOR: Continue converting Legacy data; 2nd PACES workshop planned for FY13 as part of collaboration with academia; conduct research using modern analytical tools; PCOR to end FY13. Janus: Complete development of the Janus CTR @ NIH/NCI in FY13; complete 5-yr strategic plan; initiate development planning for Janus infrastructure for non-clinical (Animal

Tox). SE: Continue to add "room" to the scientific enclave to allow cross-center and inter-agency collaboration. DCM: Data center consolidation and migration (DCM) to a modernized platform completion in FY12. HPC: Develop Elasitc Cloud and Mobile High Performance Computer (HPC) in FY12 and maintain in FY13 using Medical Counter Measures funding. DR: Develop virtual server Disaster Recovery plans for the Agency; also use for scientific computing.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2011-08-08

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$31.6	$0.5	$0.5	$1.5
DME (Excluding Planning) Costs:	$131.2	$6.5	$8.8	$7.6
DME (Including Planning) Govt. FTEs:	$8.0	$0.4	$0.4	$0.6
Sub-Total DME (Including Govt. FTE):	$170.8	$7.4	$9.7	$9.7
O & M Costs:	$19.8	$58.9	$58.5	$0.2
O & M Govt. FTEs:	$1.0	$1.6	$0.1	$0.1
Sub-Total O & M Costs (Including Govt. FTE):	$20.8	$60.5	$58.6	$0.3
Total Cost (Including Govt. FTE):	$191.6	$67.9	$68.3	$10.0
Total Govt. FTE costs:	$9.0	$2.0	$0.5	$0.7
# of FTE rep by costs:	44	15	4	6
Total change from prior year final President's Budget ($)		$-1.2	$-3.9	
Total change from prior year final President's Budget (%)		-1.67%	-5.41%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

The decrease in overall costs is primarily due to reducing the FTE cost $0.130M/FTE from $0.250M which reduces FTE overall budget. Additionally, starting FY13 and out, FTE costs increase 2.5%/year. FY13=$0.133M; FY14=$0.137M; FY15=$0.140M; and FY16=$0.143M.

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded		HHS0001	HHSF223200850014I	7524							
Awarded		HHSF223201000072C									
Awarded		HHSF223010002T	HHSF223201000039I	7524							
Awarded		HHSF223010003T	HHSF223200850012I	7524							
Awarded		HHSN261200800001E									
Awarded		HHSF223010006T	HHSF223200950026I	7524							
Awarded		HHSP233200900392G	GS35F0060L	7555							

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:
Contract ID 274288 and the two pre-award post solicatiation contracts are equipment and installation purchases through NASA SEWP task order; no EVM requirement for equipment and installation.

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-07-23

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
283467	American Recovery and Reinvestment Act Patient Centered Outcomes Research (ARRA PCOR)	FDA houses the largest known repository of clinical study data, including unique high quality data on the safety, effectiveness and performance of drugs, biologics and devices, both pre- and post approval. These data are not collected or stored in standardized format and, for this reason, cannot be evaluated across multiple studies, products or populations except with great difficulty. The goal of this project is to develop and use the standards, infrastructure (including repository and scientific capacity), tools and policies needed for FDA to receive, process and analyze study data, including analyses for comparative effectiveness research. The infrastructure and approaches developed will enable more efficient and effective review of regulated products data and the conduct of complex regulatory research,			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		including PCOR using the agency's vast, but untapped, stores of patient safety and clinical efficacy data. New scientific approaches and expertise, data standards, infrastructure, tools and capabilities will be essential to manage the increasingly complex and voluminous information submitted to the FDA in support of regulatory actions, as well as in Patient-Centered Outcome Research, PCOR (formerly known as Comparative Effectiveness Research, CER) analyses (i.e. across products, studies and populations) in non-FDA data. Thus, as part of this project, FDA is developing the appropriate infrastructure, tools and capabilities, as well as creating a Partnership in Applied Comparative Effectiveness Science for Medical Products (PACES) to support development and evaluation of comparative effectiveness approaches, and best practices and guidelines for conducting cross study comparisons. The work intends to inform medical practice with respect to benefits and best use strategies for existing therapies in particular patient populations to address which treatment works best, for whom, and under what circumstances. Additionally, development of innovative study design methods will enable more comprehensive comparisons of new therapies with those already in use, allowing both existing and			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		novel therapies to be targeted to maximize benefit and minimize risk. Collaborations with academic or other non-governmental groups, including developmental research, support of public workshops and training programs will be developed and integrated to achieve these goals.			
289545	Janus Clinical Trials Repository (CTR)	At its full capacity, Janus, the repository of structured standardized study data, will be a comprehensive clinical trial and population health data warehouse environment that will allow the routine conduct of cross-study analysis, including patient centered outcomes research, while reducing the time needed for reviewers and researchers to locate, access and perform data clean up activities to be able to use the data. Janus will provide access to and analysis of 21st century data sources (e.g., large quantity digital data that come from new imaging and “omics” technologies), and collation of that data with other sources of information on medical product effectiveness, safety, and quality. Janus will be interoperable with other data sources (e.g. electronic health record), and will include protocols for secure and reliable data storage and access, and analytic tools for data analysis. Janus will provide infrastructure, tools, and capabilities to enable new scientific approaches needed to			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		manage the increasingly complex and voluminous information submitted to the FDA in support of regulatory actions. Janus will also support the conduct of patient centered outcomes research by providing access to untapped sources of patient safety and clinical efficacy data that inform on which treatment may work best, for whom, and under what circumstances.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
283467	American Recovery and Reinvestment Act Patient Centered Outcomes Research (ARRA PCOR)							
289545	Janus Clinical Trials Repository (CTR)							

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
289545	289545: Janus Infrastructure (CTR): Janus Phase 3A @ NCI		2010-05-31	2010-05-31	2010-05-31	272	0	0.00%
283467	283467: Modern Analytical Tools: Hardware Acquisiiton		2010-09-20	2010-09-20	2010-09-20	61	0	0.00%
283467	283467: ARRA		2010-09-24	2010-09-24	2010-09-24	280	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	PCOR: Gather Requirements							
283467	283467: PACES: Workshop #1		2011-02-07	2011-02-07	2011-02-07	54	0	0.00%
289545	289545: Janus Planning FY11: Strategic Plan/ Road Map		2011-03-31	2011-03-31	2011-03-31	181	0	0.00%
283467	283467: PACES: PCOR Study #1: Proposal		2011-05-12	2011-05-12	2011-05-12	72	0	0.00%
283467	283467: PACES: PCOR Study Design #2: Proposal		2011-05-12	2011-05-12	2011-05-12	72	0	0.00%
289545	289545: Janus CTR Release 3 (R3): Deliver Extract & Load Service, v2		2011-06-03	2011-06-03	2011-06-03	60	0	0.00%
283467	283467: PACES: PCOR Study #2: Proposal		2011-09-14	2011-09-14	2011-09-14	75	0	0.00%
283467	283467: PACES: PCOR Study Design#1: Proposal		2011-09-23	2011-09-23	2011-09-23	53	0	0.00%
289545	289545: Janus Planning: Center-Specific CONOPS (CDER Clinical)		2011-09-30	2011-09-30	2011-09-30	364	0	0.00%
289545	289545: Janus Infrastructure (CTR): Interface to Janus - CDER FY11		2011-09-30	2011-09-30	2011-09-30	364	0	0.00%
289545	289545: Janus CTR R1: Deliver Solution Architecture, v1		2011-09-30	2011-09-30	2011-09-30	163	0	0.00%
289545	289545: Janus Planning: Study Data		2011-09-30	2011-09-30	2011-09-30	364	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	Standards Dev							
289545	289545: Janus Planning: Platform Hosting		2011-12-03	2011-12-03	2011-12-03	124	0	0.00%
289545	289545: Janus CTR R1: Design Conceptual Data Model		2011-12-16	2011-12-16	2011-12-16	224	0	0.00%
289545	289545: Janus CTR R1: Complete CTR Security & Implementation Planning		2011-12-30	2011-12-30	2011-12-30	151	0	0.00%
289545	289545: Janus CTR Release 4 (R4): Deliver Data Mart		2011-12-31	2011-12-31	2011-12-31	208	0	0.00%
289545	289545: Janus CTR R1: Roll Out Release 1 Environment		2012-01-16	2012-01-16	2012-01-16	206	0	0.00%
289545	289545: Janus CTR R1: Deliver CTR Validation Service		2012-01-17	2012-01-17	2012-01-17	256	0	0.00%
289545	289545: Janus CTR R1: Design Logical Data Model		2012-03-08	2012-03-08	2012-03-08	209	0	0.00%
289545	289545: Janus CTR R1: Implement Physical Database Model		2012-03-29	2012-03-29	2012-03-29	97	0	0.00%
289545	289545: Janus CTR R1: Deploy Release 1 Solution		2012-03-29	2012-03-29	2012-03-29	71	0	0.00%
283467	283467: Legacy Data Conversion: Phase II - Delivery of Converted Data Sets		2012-03-30	2012-03-30	2012-03-30	211	0	0.00%
289545	289545: Janus Infrastructure (CTR):		2012-03-31	2012-03-31	2012-03-30	182	1	0.55%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	Interface to Janus - CDER FY12							
283467	283467: PACES: Workshop #2		2012-05-04	2012-05-04	2012-05-04	154	0	0.00%
289545	289545: Janus CTR R2: Complete CTR Load Service v1		2012-05-20	2012-05-20	2012-05-20	243	0	0.00%
289545	289545: Janus CTR R2: Deliver Final Solution Architecure		2012-05-30	2012-05-30		135	-93	-68.89%
289545	289545: Janus CTR R2: Complete CTR Extraction Service		2012-05-30	2012-05-30	2012-05-30	272	0	0.00%
283467	283467: Legacy Data Conversion: Phase III - Delivery of Converted Datasets		2012-08-31	2012-08-31		151	0	0.00%

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
HPC: Decrease time a batch job waits before resources become available on a cluster	Hours	Mission and Business Results - Services for Citizens	Under target	36.000000	24.000000	24.000000	24.000000	Semi-Annual
HPC: Increase aggregarte avilability of spare capacity across all clusters.	%	Process and Activities - Productivity	Over target	3.000000	5.000000	5.000000	8.000000	Monthly
HPC: Increase immunity for running jobs from power outgages lasting up to 6 minutes	%	Mission and Business Results - Services for Citizens	Over target	85.000000	100.000000	100.000000	100.000000	Semi-Annual
SE: Increase the number of SE rooms	# of SE Rooms	Process and Activities - Management and Innovation	Over target	0.000000	1.000000	1.000000	3.000000	Quarterly
SE: maintain optimal response time as new rooms are added to the Scientific Enclave.	seconds	Technology - Reliability and Availability	Under target	10.000000	10.000000	10.000000	10.000000	Monthly
DCM: Median Hours to respond and resolve Severity One outages	Number	Customer Results - Timeliness and Responsiveness	Under target	3.500000	3.500000	3.500000	3.250000	Monthly
DCM: Percentage of uptime at Contractor Host Data Center (CHDC) Platform Reliablity	%	Customer Results - Service Quality	Over target	99.990000	99.992000	99.992000	99.993000	Monthly
DCM: Percentage of uptime of FDA Critical Applications	%	Customer Results - Service Quality	Over target	99.900000	99.200000	99.200000	99.300000	Monthly